

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Claim 1 (currently amended): A kit, comprising as separate components:

a) a first composition comprising capsaicin or a capsaicin analog for application of the capsaicin or capsaicin analog to a bodily surface; and

b) a second composition for cleansing the bodily surface comprising a substance in which the capsaicin or capsaicin analog ~~is soluble~~ has a solubility of at least about 10 percent w/w.

Claim 2 (cancelled)

Claim 3 (original): The kit of claim 1 wherein the second composition comprises a substance in which said capsaicin or analog has a solubility of at least about 20 percent w/w.

Claim 4 (original): The kit of claim 1 wherein the second composition comprises a substance in which capsaicin or analog has a solubility of at least about 25 percent w/w.

Claim 5 (original): The kit of claim 1 wherein the second composition comprises polyethylene glycol and a polyacrylate thickening polymer.

Claim 6 (original): The kit of claim 1 wherein the second composition comprises:

a) about 60 to about 99 percent w/w polyethylene glycol (PEG);

b) about 0.1 to about 4.0 percent w/w polyacrylate thickening agent; and

c) the balance water; wherein the composition is at a pH between about 6.0 and about 8.0.

Claim 7 (original): The kit of claim 6 wherein the second composition comprises

- a) about 84 to about 94 percent w/w polyethylene glycol;
- b) about 0.1 to about 2.0 percent w/w polyacrylate thickening agent; and
- c) the balance water; wherein the composition is at a pH of about 7.0 to 7.5.

Claim 8 (original): The kit of claim 7 wherein the second composition further comprises:

- d) about 0.005 to about 0.05 percent w/w butylated hydroxyanisole; and
- e) about 0.05 to about 0.5 percent w/w edetate sodium.

Claim 9 (original): The kit of claim 1 further comprising a third composition, wherein said third composition comprises an anesthetic.

Claim 10 (original): The kit of claim 1 further comprising instructions for use.

Claim 11 (original): The kit of claim 1 wherein the first composition comprises capsaicin or a capsaicin analog at a concentration of about 0.001 to about 60 percent w/w.

Claim 12 (original): The kit of claim 1 wherein the first composition comprises capsaicin or a capsaicin analog at a concentration of about 1.0 to about 10 percent w/w.

Claim 13 (original): The kit of claim 1 wherein the first composition comprises capsaicin or a capsaicin analog at a concentration of about 5 to about 10 percent w/w.

Claim 14 (original): The kit of claim 1 wherein the first composition comprises capsaicin or a capsaicin analog contained in a patch.

Claim 15 (original): The kit of claim 14 wherein the capsaicin or analog is present in the patch at an amount of about 0.64 mg/cm².

Claim 16 (currently amended): A kit, comprising:

a) a first composition comprising a patch comprising capsaicin or capsaicin analog at an amount of about 0.64 mg/cm²;

b) a second composition comprising a cleansing gel comprising:

i) about 84 to about 94 percent w/w polyethylene glycol;

ii) about 0.1 to about 2.0 percent w/w polyacrylate thickening agent; and

iii) about 0.005 to about 0.05 percent w/w butylated hydroxyanisole;

iv) about 0.05 to about 0.5 percent w/w edetate sodium; and

v) the balance water;

wherein the second composition is at a pH of about 7.0 to 7.7 and is capable of solubilizing at least about 10 percent w/w of capsaicin or the capsaicin analog.

Claim 17 (currently amended): A composition for cleansing a bodily surface comprising:

a) about 60 to about 99 percent w/w polyethylene glycol (PEG);

b) about 0.1 to about 4.0 percent w/w polyacrylate thickening agent; and

c) the balance water; wherein the composition is at a pH between about 6.0 and about 8.0 and is capable of solubilizing at least about 10 percent w/w of capsaicin or the capsaicin analog.

Claim 18 (original): The composition of claim 17 comprising:

a) about 84 to about 94 percent w/w polyethylene glycol (PEG);

b) about 0.1 to about 2.0 percent w/w polyacrylate thickening agent; and

c) the balance water; wherein the composition is at a pH between about 7.0 and about 7.7.

Claim 19 (original): The composition of claim 18 further comprising a stabilizer.

Claim 20 (original): The composition of claim 19 further comprising a cooling agent.

Claim 21 (original): The composition of claim 19 comprising:

- a) about 87 to about 91 percent w/w polyethylene glycol;
- b) about 0.3 to about 1.5 percent w/w polyacrylate thickening agent;
- c) about 0.01 to about 0.03 percent w/w butylated hydroxyanisole;
- d) about 0.02 to about 0.2 percent w/w edetate sodium; and
- e) the balance water; wherein the composition is at a pH of about 7.0 to about 7.7.

Claim 22 (original): The composition of claim 21 comprising:

- a) about 89.08 percent w/w PEG 300;
- b) about 1.0 percent w/w polyacrylate thickening agent;
- c) about 0.02 percent w/w butylated hydroxyanisole;
- d) about 0.1 percent w/w disodium edetate; and
- e) the balance water; wherein the composition is at a pH of about 7.5.

Claim 23 (currently amended): A method for treating pain in an individual in an area of the body affected by pain, comprising:

- a) administering an afferent nerve fiber blocking regional anesthetic to the affected area;

b) affixing to the affected area a device, wherein said device comprises a skin-adherent patch, the patch including a reservoir comprising a therapeutic formulation whereby said formulation is continuously provided to the surface of the skin for a predetermined period of time, wherein said formulation comprises capsaicin or a capsaicin analog in a total concentration from greater than about 5% to 10% by weight of the formulation, wherein a single administration of said patch affords significant relief of said pain to said individual for at least several weeks; and

c) cleansing the area to which the patch of step b) has been applied by

i) applying to the area a composition comprising about 80 to about 99 percent w/w polyethylene glycol; about 0.1 to about 2.0 percent w/w polyacrylate thickening agent; and the balance water; wherein the composition is at a pH of about 7.0 to about 7.7 and is capable of solubilizing at least about 10 percent w/w of capsaicin or the capsaicin analog; and

ii) removing the composition of step (c) from the area.

Claim 24 (currently amended): A method for cleansing a bodily surface that has been contacted with an irritating or painful substance, comprising:

a) applying to the bodily surface a composition comprising:

i) about 80 to about 99 percent w/w polyethylene glycol;

ii) about 0.1 to about 2.0 percent w/w polyacrylate thickening agent; and

iii) the balance water; wherein the composition is at a pH of about 7.0 to about 7.7 and is capable of solubilizing at least about 10 percent w/w of capsaicin or the capsaicin analog; and

b) removing the composition of step (a) from the bodily surface.

Claim 25 (withdrawn): A method for treating an individual in need of treatment for a capsaicin-responsive condition comprising

(a) applying a first composition comprising capsaicin or a capsaicin analog to a bodily surface;

(b) applying a second composition in which capsaicin has a solubility of at least about 10% w/w to the bodily surface; and

(c) removing the second composition from the bodily surface.

Claim 26 (withdrawn): The method of claim 25 further comprising administering an anesthetic to the individual prior to or simultaneously with the application of the first composition.

Claim 27 (withdrawn): The method of claim 26 wherein the anesthetic is contained in a lotion or gel.

Claim 28 (withdrawn): The method of claim 25 wherein the first composition is applied by affixing a skin-adherent patch containing the first composition to the bodily surface.

Claim 29 (withdrawn): The method of claim 28 further comprising administering an anesthetic to the individual prior to or simultaneously with the application of the skin-adherent patch.

Claim 30 (withdrawn): The method of claim 28 wherein the skin-adherent patch contains from the 5% to about 10% capsaicin.

Claim 31 (withdrawn): The method of claim 25 wherein capsaicin has a solubility of at least about 20% (w/w) in the second composition.

Claim 32 (withdrawn): The method of claim 25 wherein the second composition comprises at least 60% (w/w) polyethylene glycol.

Claim 33 (withdrawn): The method of claim 25 wherein the capsaicin-responsive condition is selected from the group consisting of neuropathic pain, pain produced by mixed

nociceptive and/or neuropathic mixed etiologies, inflammatory hyperalgesia, dermatitis, pruritis, itch, psoriasis, warts, headaches, wrinkles and skin cancer.

Claim 34 (previously presented): A method for cleansing a bodily surface that has been contacted with capsaicin or a capsaicin analog comprising:

- a) applying to a bodily surface a composition in which capsaicin has a solubility of at least about 10% w/w; and
- b) removing said composition from the bodily surface.

Claim 35 (previously presented): The method of claim 34 wherein the substance is capsaicin.

Claim 36 (previously presented): The method of claim 34 wherein capsaicin has a solubility of at least about 20% w/w in the composition.

Claim 37 (previously presented): The method of claim 34 wherein the composition comprises about 60 to about 99 percent w/w polyethylene glycol.

Claim 38 (previously presented): The method of claim 37 wherein the composition further contains about 0.1 to about 4 percent w/w thickening agent, and the balance water.

Claim 39 (previously presented): The method of claim 37 wherein the composition contains about 80 to about 99 percent w/w polyethylene glycol.

Claim 40 (previously presented): The method of claim 39 wherein the composition further contains about 0.1 to about 2 percent w/w polyacrylate thickening agent and the balance water.

Claim 41 (previously presented): The method of claim 37 wherein the composition contains about 87 to about 91 percent w/w polyethylene glycol.

Claim 42 (previously presented): The method of claim 41 wherein the composition further contains about 0.3 to about 1.5 percent w/w polyacrylate thickening agent and the balance water.

Claim 43 (previously presented): The method of claim 42 wherein the composition is at a pH of about 7.0 to about 7.7.

Claim 44 (previously presented): The method of claim 43 wherein the composition further contains about 0.01 to about 0.03 percent w/w butylated hydroxyanisole, about 0.02 to about 0.2 percent w/w EDTA/EDTA salts, and the balance water.